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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
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November 26, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

02-SWR-WL-08/0

Georgia Blobaum
Site Administrator
Advanced Medical Imaging
7601 Pioneers Blvd.
Lincoln, NE 68516

RE: Inspection ID - 2249030001

Dear Ms. Blobaum,

On November 7, 2001, a representative of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility.

The Mammography Quality Standards Act of 1992 requires your facility to meet specific standards. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 finding at your facility:

Level 1: Mammograms were processed in processor 1, Fuji, FPM 6000 SP, when it was out of limits on at least 5 days.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Level 1 findings may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility. They represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to:

- Placing your facility under a Directed Plan of Correction.
- Charging your facility for the cost of on-site monitoring.

- Assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- Suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the level 2 findings that were listed on the inspection report provided to you at the close of the inspection. The inspection revealed the following level 2 findings:

Level 2: Corrective actions for processors QC failures were not documented at least once for processor 1, Fuji, FPM 6000 SP.

Level 2: Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 2, Instrumentarium Imaging Corp., PERF, room #2.

Level 2: Phantom QC records were missing for at least two weeks but less than four weeks for unit 2, Instrumentarium Imaging Corp., PERF, room #2.

Level 2: Phantom QC records were missing for at least two weeks but less than four weeks for unit 3, Instrumentarium Imaging Corp., PERF, room #3.

Level 2: Phantom QC records were missing for at least two weeks but less than four weeks for unit 4, Instrumentarium Imaging Corp., PERF, room #4.

Level 2: Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 3, Instrumentarium Imaging Corp., PERF, room #3.

Level 2: The medical physicist's survey for x-ray unit 2, Instrumentarium Imaging Corp., PERF, room #2 is incomplete because the following tests were inadequate or not done:
No artifact evaluation
No beam quality (HVL) measurement:
-Numerical results were not given.

Level 2: The medical physicist's survey for x-ray unit 3, Instrumentarium Imaging Corp., PERF, room 3 is incomplete because the following tests were inadequate or not done:
No artifact evaluation
No beam quality (HVL) measurement:
-Numerical results were not given.

Level 2: The medical physicist's survey for x-ray unit 4, Instrumentarium Imaging Corp., PERF, room 4 is incomplete because the following tests were inadequate or not done:
No artifact evaluation
No beam quality (HVL) measurement:
-Numerical results were not given.

It is necessary for you to act on this matter immediately. You are required to respond to this office in writing within fifteen (15) working days from receipt of this letter. Please address the following:

- The specific steps you have taken to correct all of the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.
- Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate.
- Sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:
Deborah M. McGee, Radiation Specialist
Food and Drug Administration
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982

This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Deborah M. McGee at (214) 655-8100 ext. 138.

Sincerely yours,

Gary L. Pierce
Regional Food and Drug Director